

HTANGEL

KEEPING YOU UP-TO-DATE ON
INTERNATIONAL HTA DECISIONS

Issue 27: July 2025

2x more approvals than non-approvals this month!

This newsletter summarises final decisions from HTA bodies around the world from published reports in July 2025.

Good news for: **Dapagliflozin**, approved for chronic kidney disease in England and South Korea and for chronic heart failure in South Korea; **Isatuximab**, approved for multiple myeloma in Germany and no need to submit in Wales; and **Pembrolizumab**, approved for endometrial cancer in Scotland and no need to submit in Wales.

Mixed news for: **Amivantamab with Lazertinib**, approved for non-small-cell lung cancer in Germany but not in Scotland; **Osimertinib**, approved under patient access scheme for non-small-cell lung cancer in Scotland but not approved in Germany; and **Ravulizumab**, approved for paroxysmal nocturnal haemoglobinuria and atypical haemolytic uremic syndrome in South Korea but not approved for atypical uremic haemolytic syndrome in Brazil.

Bad news for: **Lecanemab**, not approved for mild cognitive impairment in Alzheimer's dementia in Japan and Scotland; **Lisocabtagen maraleucel**, not approved for non-Hodgkin lymphoma in Germany and application terminated in England; and **Nivolumab**, not approved for oesophageal cancer in Brazil.

“

51 Approvals

22 with special arrangements

“

24 Not approved

9 Excluded

4 Terminated

“

2 Evidence reviews

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Pharmacological Technologies



Korea
HIRA

Blood
Anaemia
IRON INJECTIONS

✓ Approved



Korea
HIRA

Blood
Immune
thrombocytopenia
FOSTAMATINIB DISODIUM
HEXAHYDRATE

✓ Approved



Brazil
CONITEC

Blood
Atypical uremic
haemolytic syndrome
RAVULIZUMAB

✗ Not
approved



Korea
HIRA

Blood
Paroxysmal nocturnal
haemoglobinuria
IPTACOPAN

✓ Approved
with special
conditions



Brazil
CONITEC

Blood
Haemophilia A
EMICIZUMAB

✗ Not
approved



Korea
HIRA

Blood
Paroxysmal nocturnal
haemoglobinuria
PEGCETACOPLAN

✓ Approved
with special
conditions



Korea
HIRA

Blood
Immune
thrombocytopenia
AVATROMBOPAG MALEATE

✓ Approved



Korea
HIRA

Blood
Paroxysmal nocturnal
haemoglobinuria, Atypical
Haemolytic Uremic Syndrome
RAVULIZUMAB

✓ Approved

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Pharmacological Technologies

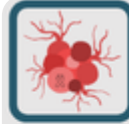


Korea
HIRA



Blood, Neurology

Paroxysmal nocturnal haemoglobinuria,
Haemolytic uremic syndrome,
Neuromyelitis optical spectrum disorder
ECULIZUMAB



Wales
AWTTC 5392

Cancer

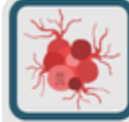
Endometrial cancer
PEMBROLIZUMAB,
CARBOPLATIN, PACLITAXEL



Germany
IQWiG A25-50

Cancer

Chronic lymphocytic
leukaemia
PIRTOBRUTINIB



Germany
IQWiG A25-47

Cancer

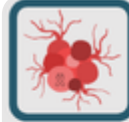
Follicular lymphoma
LISOCABTAGEN
MARALEUCEL



England
NICE TA1079

Cancer

Colorectal cancer
FRUQUINTINIB



Wales
AWTTC 3862

Cancer

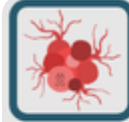
Hepatocellular carcinoma
DURVALUMAB,
TREMELIMUMAB



Scotland
SMC2767

Cancer

Endometrial cancer
PEMBROLIZUMAB,
CARBOPLATIN, PACLITAXEL



Brazil
CONITEC

Cancer

Leukaemia
ARSENIC TRIOXIDE



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Pharmacological Technologies



Wales
AWTTC 5288

Cancer
Lung cancer
ADAGRASIB



Germany
IQWiG A25-77

Cancer
Lung cancer
LAZERTINIB,
AMIVANTAMAB



England
NICE TA1076

Cancer
Lung cancer
ADAGRASIB



Germany
IQWiG A25-03

Cancer
Lung cancer
OSIMERTINIB



Germany
IQWiG A25-78

Cancer
Lung cancer
LAZERTINIB,
AMIVANTAMAB



Scotland
SMC2736

Cancer
Lung cancer
OSIMERTINIB,
PEMETREXED, PLATINUM-
BASED CHEMOTHERAPY



Scotland
SMC2758

Cancer
Lung cancer
AMIVANTAMAB,
CARBOPLATIN,
PEMETREXED



Wales
AWTTC 5340

Cancer
Lung cancer
TARLATAMAB



HTANGEL

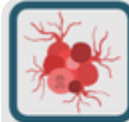
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Pharmacological Technologies



England
NICE TA1081

Cancer
Lymphoma
ZANUBRUTINIB



England
NICE TA1083

Cancer
Non-Hodgkin's
lymphoma
LISOCABTAGENE
MARALEUCAL



England
NICE TA1084

Cancer
Multiple myeloma
IDECABTAGENE
VICLEUCAL



Brazil
CONITEC

Cancer
Oesophageal cancer
NIVOLUMAB



Germany
IQWiG A25-20

Cancer
Multiple myeloma
ISATUXIMAB, BORTEZOMIB,
LENALIDOMIDE,
DEXAMETHASONE



Brazil
CONITEC

Cancer
Oesophageal cancer
NIVOLUMAB,
PEMBROLIZUMAB



Wales
AWTTC 4113

Cancer
Multiple myeloma
ISATUXIMAB, BORTEZOMIB,
LENALIDOMIDE, DEXAMETH
ASONE



Brazil
CONITEC

Cancer
Prostate cancer
ABEMACICLIB



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Pharmacological Technologies



Germany
IQWiG A25-45

Cancer
Renal cancer
BELZUTIFAN



Germany
IQWiG A25-44

Cancer
Von Hippel-Lindau
disease
BELZUTIFAN



Germany
IQWiG A25-45

Cancer
Renal cancer
BELZUTIFAN



Korea
HIRA

Cardiovascular
Pulmonary embolism
ALTEPLASE



Germany
IQWiG A25-45

Cancer
Renal cancer
BELZUTIFAN



Korea
HIRA

Cardiovascular,
Genitourinary
Chronic heart failure,
Chronic kidney failure
DAPAGLIFLOZIN



Scotland
SMC2733

Cancer
Thyroid cancer
SELPERCATINIB



Scotland
SMC2798

Endocrine
Menopause
FEZOLINETANT



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Pharmacological Technologies



Wales
AWTTC 3989

Gastrointestinal
Crohn's disease
GUSELKUMAB



Excluded



England
NICE TA1080

Gastrointestinal
Crohn's disease
MIRIKIZUMAB



Approved
with special
conditions



Wales
AWTTC 4713

Gastrointestinal
Ulcerative colitis
GUSELKUMAB



Excluded



Korea
HIRA

Gastrointestinal,
Musculoskeletal, Skin
Autoimmune disorders, Atopic
dermatitis, Inflammatory disorders
UPADACITINIB



Approved
with special
conditions



Germany
IQWiG A25-46

Genetic & Metabolic
Amyloidosis
ACORAMIDIS



Not
approved



France
HAS AP451

Genetic & Metabolic
Amyloidosis
EPLONTERSEN



Not
approved



England
NICE TA1085

Genetic & Metabolic
Cystic fibrosis
VANZACAFTOR,
TEZACAFTOR,
DEUTIVACAFTOR



Approved
with special
conditions



Wales
AWTTC 5390

Genetic & Metabolic
Cystic fibrosis
VANZACAFTOR,
TEZACAFTOR,
DEUTIVACAFTOR



Excluded

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Pharmacological Technologies



England
NICE TA1075

Genitourinary
Chronic kidney
disease
DAPAGLIFLOZIN



England
NICE TA1082

Infection,
Genitourinary
Cytomegalovirus
LETERMOVIR



Korea
HIRA

Infection
Candida,
Aspergillosis
ANTIFUNGAL AGENTS



Korea
HIRA

Infection, Neurology, Blood, Cardiovascular, Skin,
Other
Hypogammaglobulinaemia, GBS, Sepsis, ITP, KD, PM, DM, MG,
Neonatal immune haemolytic disease, TEN, SJS, CIDP,
Autoimmune encephalitis, SLE, MIS
HUMAN IMMUNOGLOBULIN
G INJECTION



Brazil
CONITEC

Infection
Meningococcal B
MENINGOCOCCAL B
ADSORBED VACCINE



Scotland
SMC2764

Musculoskeletal
Osteoporosis
ABALOPARATIDE



Korea
HIRA

Infection
Paediatric multisystem
inflammatory syndrome
METHYLPREDNISOLONE
SODIUM SUCCINATE



Korea
HIRA

Musculoskeletal, Gastrointestinal, Cancer,
Pregnancy, Skin, Eye
Rheumatoid arthritis, Ankylosing spondylitis,
Psoriatic arthritis, Crohn's disease, Ectopic
pregnancy, Graft-versus-host disease, Atopic
dermatitis
METHOTREXATE



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Pharmacological Technologies



Scotland
SMC2811

Neurology
Alzheimer's disease
LECANEMAB

Not approved



England
NICE TA753

Neurology
Focal onset seizures
CENOBAMATE

Approved with special conditions



Korea
HIRA

Other
Autoimmune disorders
MYCOPHENOLATE
MOFETIL

Approved



France
HAS AP463

Other
Graft-versus-host disease
BELUMOSUDIL

Not approved



Brazil
CONITEC

Pregnancy
Contraception
ETONOGESTREL

Approved



Brazil
CONITEC

Pregnancy
Contraception
ETONOGESTREL

Approved



Korea
HIRA

Pregnancy, Skin
Preterm labour,
Reynaud's phenomenon
NIFEDIPINE

Approved



Wales
AWTTC 3859

Respiratory
Allergic rhinitis,
Conjunctivitis, Allergic
conjunctivitis
BETULA VERRUCOSA

Excluded

Pharmacological Technologies



**Korea
HIRA**

Respiratory
Chronic fibrotic
interstitial lung disease
NINTEDANIB



**England
NICE TA1077**

Skin
Atopic dermatitis
NEMOLIZUMAB



**Korea
HIRA**

Skin
Atopic dermatitis
ABROCITINIB



**Korea
HIRA**

Skin
Atopic dermatitis
TRALOKINUMAB



**Korea
HIRA**

Skin
Atopic dermatitis
DUPIUMAB



**Korea
HIRA**

Skin
Atopic dermatitis
LEBRIKIZUMAB



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Non-pharmacological Technologies



Korea
NECA HTA-2025-19

Cancer
Ovarian cancer
NEXT-GENERATION
SEQUENCING

Not approved



Brazil
CONITEC

Cardiovascular
Patient ductus arteriosus
CARDIOVASCULAR
IMPLANT

Approved



England
NICE IPG806

Cardiovascular
Atrial fibrillation
PULSE-FIELD
ABLATION

Approved



England
NICE HTE28

Genitourinary
Chronic incomplete
bladder emptying
URETHRAL CATHETERS

Approved with special conditions



Korea
NECA Innovation-
2025-5

Cardiovascular
Large vessel
occlusion
AI-BASED SCREENING

Approved



England
NICE HTE30

Mental Health
Depression, Anxiety
DIGITAL FRONT DOOR
TECHNOLOGY

Approved with special conditions



Scotland
SHTG

Cardiovascular
Paroxysmal atrial
fibrillation
ECG PATCH MONITOR

Approved



Korea
NECA HTA-2025-18

Musculoskeletal
Back pain
INTRADISCAL INJECTION
OF BONE MARROW
ASPIRATE

Not approved

Non-pharmacological Technologies



Korea
HIRA

Musculoskeletal
Osteoarthritis
COLLAGEN

 Not
approved



Korea
HIRA

Musculoskeletal
Osteoarthritis
SODIUM
POLYNUCLEOTIDE

 Approved
with special
conditions



England
NICE HTE29

Surgery
Colostomy
ONE-PIECE CLOSED
BAGS

 Approved
with special
conditions



Korea
NECA HTA-2025-20

Surgery
Intestinal anastomosis
EXTRAPERITONEAL
TUNNELING DRAIN
INSERTION

 Not
approved

Diagnostic Testing

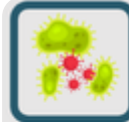


**Korea
HIRA**

**Cancer
Brain cancer
POSITRON EMISSION
TOMOGRAPHY**



Approved



**Brazil
CONITEC**

**Infection
Histoplasmosis
ENZYME
IMMUNOASSAY**



**Not
approved**



**Korea
HIRA**

**Cancer
Cancer
GENETIC TESTING**



Approved



**Korea
HIRA**

**Cardiovascular
Congenital heart disease
OXYGEN
SATURATION TEST**



Approved



**Brazil
CONITEC**

**Gastrointestinal
Liver transplant
rejection
C4D RESEARCH**



Approved

Other Guidance



Canada
INESSS

Gastrointestinal

Gastroesophageal reflux
disorder, Dyspepsia
PROTON PUMP INHIBITORS



**Evidence
review**



Japan
C2H 2308

Neurology

Alzheimer's disease
LECANEMAB



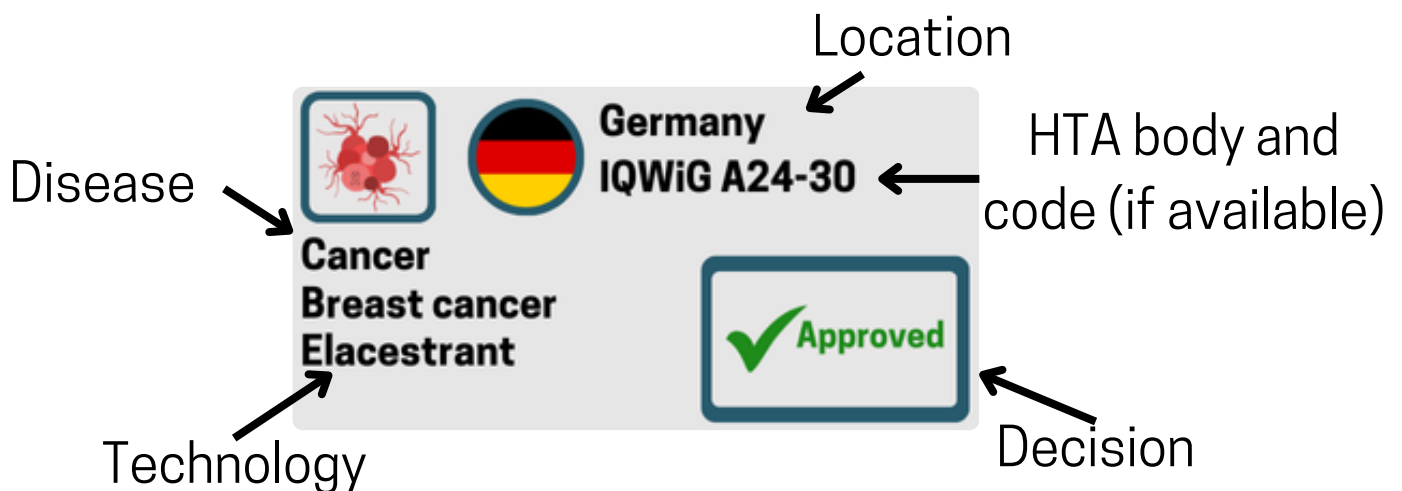
**Evidence
review**

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Further Information

HTAngel is designed to help keep you up to date with the latest HTA decisions around the world. Below is a breakdown of the tiles in the newsletter.



At Crystallise we aim to provide an innovative approach to processing information, using software tools to automate processes that are slower and less accurate when done by humans. Our approach provides clients with greater transparency and scope than they could find for the same budget elsewhere. We work with a network of experts and organisations that help us support clients efficiently and effectively, and are proud of our flexible and ingenious way of solving their problems.

For further information about HTAngel contact
newsletter@crystallise.com

To speak to us about our services contact
contact@crystallise.com